UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

GLADYS E. KATSIAFAS,
Plaintiff,

v. Case No: 2:19-cv-822-FtM-60MRM

C. R. BARD, INC.,
Defendant.

ORDER GRANTING IN PART, AND DENYING IN PART, "DEFENDANT C. R. BARD'S MOTION TO EXCLUDE OR LIMIT THE OPINIONS AND TESTIMONY OF LENNOX HOYTE, M.D."

This matter is before the Court on "Defendant C. R. Bard's Motion to Exclude or Limit the Opinions and Testimony of Lennox Hoyte, M.D." and its memorandum in support, filed by counsel on August 15, 2019. (Docs. 62; 63). On August 29, 2019, Plaintiff Gladys Katsiafas filed her response in opposition to the motion. (Doc. 65). On September 16, 2019, Defendant filed a reply. (Doc. 69). On January 28, the Court held a hearing to address this matter. *See* (Doc. 104). After reviewing the motion, response, reply, arguments, court file and record, the Court finds as follows:

Background

This case is one of thousands of similar cases filed since approximately October 2010.[1] Plaintiff Gladys Katsiafas directly filed this product liability case in

[1] In the seven MDLs, over 100,000 cases have been filed, approximately 15,000 of which are in the Bard MDL. *See* MDL 2187 (C.R. Bard) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2187; MDL 2325 (American Medical Systems) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2325; MDL 2326 (Boston Scientific) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2326; MDL 2327 (Johnson & Johnson, Ethicon) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2327; MDL 2387 (Coloplast) Member List of Cases,

the Southern District of West Virginia as part of the multidistrict litigation (MDL) entitled *In re: C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2187. The case was not resolved by the MDL transferee court (MDL court), and it was transferred at the conclusion of the coordinated pretrial proceedings as part of Wave 9.

On June 8, 2009, Plaintiff was implanted with the Avaulta Solo Anterior Synthetic Support System (Avaulta) device at a hospital in Cape Coral, Florida. The Avaulta was designed and manufactured by Defendant. On September 11, 2009, her doctor performed a revision surgery and removed the Avaulta. On July 11, 2017, a second revision surgery was performed.

On June 6, 2013, Plaintiff filed suit directly in the MDL using a short-form complaint, alleging the following claims: Negligence (Count I), Strict Liability – Design Defect (Count II), Strict Liability – Manufacturing Defect (Count III), Strict Liability – Failure to Warn (Count IV), Breach of Express Warranty (Count V), Breach of Implied Warranty (Count VI), and Punitive Damages (Count VII).

In the motion before this Court, Defendant raises various *Daubert*[2] challenges to the proposed testimony of Dr. Lennox Hoyte, M.D. ("Dr. Hoyte"). This is not the first case where Dr. Hoyte has been proposed as an expert witness. And this is not the first time Defendant has raised similar *Daubert* challenges to his

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https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2387; MDL 2440 (Cook Medical) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2440; and MDL 2511 (Neomedic) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2511.

[2] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

testimony. Indeed, at earlier points in the MDL litigation, Defendant made some of the exact same *Daubert* arguments they make here in an attempt to exclude Dr. Hoyte's opinions. Nonetheless, Dr. Hoyte was previously qualified as an expert witness in the MDL litigation. *See, e.g.*, *In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2187, 2018 WL 4220671, at *3–5 (S.D.W. Va. Sept. 5, 2018); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 622–27 (S.D.W. Va. 2013). In fact, Dr. Hoyte testified in at least one of the bellwether trials, where it appears he was allowed to offer many of the same expert opinions that Defendant argues in the instant motion should be precluded by *Daubert*. That trial resulted in a jury verdict in favor of the plaintiff, which was subsequently affirmed by the Fourth Circuit Court of Appeals. *See In re C.R. Bard, Inc., MDL. No. 2187, Pelvic Repair Sys. Prod. Liab. Litig.*, 810 F.3d 913, 930 (4th Cir. 2016) (reviewing the expert evidence presented by the plaintiff as to the design defects, including the testimony of Dr. Lennox Hoyte).

Legal Standard

An expert witness may testify in the form of an opinion if "(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702; *see also Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993).

Functioning as a gatekeeper, the district court plays an important role by ensuring that all scientific testimony is relevant and reliable. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 601. Although *Daubert* references specific factors for the district court to consider when evaluating relevancy and reliability, "[t]he inquiry to be undertaken by the district court is a flexible one focusing on the principles and methodology employed by the expert, not on the conclusions reached." *Id.* at 601–02 (internal quotations and citations omitted).

In several *Daubert* motions – including the instant motion – "a specific scientific methodology comes into play, dealing with differential diagnoses or etiologies." *See id.* As the MDL court explained, a differential diagnosis is a scientific technique where the expert identifies the cause of a medical problem by "eliminating the likely causes until the most probable one is isolated." *See id.* (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999)). "A reliable differential diagnosis passes scrutiny under *Daubert.* An unreliable differential diagnosis is another matter" and may be excluded. *Id.* However, a district court should not exclude a medical expert's opinions if he or she has "failed to rule out every possible alternative cause of a plaintiff's illness." *Id.* (quoting *Westberry*, 178 F.3d at 265–66). Instead, "the alternative causes . . . affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony," unless the expert is unable to offer any explanation for his or her causation opinion in light of the alternative causes offered by the opposing party. *Id.* (quoting *Westberry*, 178 F.3d at 265–66).

Analysis

Plaintiff offers Dr. Hoyte as an expert in the areas of urogynecology and female pelvic medicine and reconstructive surgery, and he has been designated to provide both general and case specific expert testimony. *See* (Doc. 62-1). Defendant seeks to exclude Dr. Hoyte's opinions regarding: (1) general opinions about Bard and the Avaulta, including those regarding the FDA or regulatory actions; (2) specific causation, including that the Avaulta caused or contributed to Plaintiff's purported mesh erosion, bleeding, chronic pelvic pain, bladder control problems, bowel control problems, and dyspareunia, along with any opinions as to Plaintiff's prognosis; (3) safer alternatives to the Avaulta; and (4) the instructions for use (IFU) associated with the Avaulta, specifically that the IFU does not appropriately disclose the risks of the Avaulta. Plaintiff opposes the motion, arguing that each of these opinions is admissible. As explained below, Defendant's motion is granted in part and denied in part.

General Opinions about Bard and the Avaulta

Defendant seeks to exclude all of Dr. Hoyte's general opinions for the reasons set forth in its Wave 9 motion to exclude the same. Dr. Hoyte was disclosed as a general causation expert, and the MDL court previously made several rulings concerning his general causation testimony. *See generally In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2187, 2018 WL 4220671, at *3–5; *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 622–27. The Court finds these rulings persuasive and adopts them herein. Consequently, Defendant's request to exclude

Dr. Hoyte's general opinions is granted in part and denied in part. Dr. Hoyte is permitted qualified to give opinions regarding biomechanics and biomechanic analysis, the characteristics of polypropylene, and product design. Dr. Hoyte is not permitted to give opinions on Defendant's marketing of the Avaulta device, or the purpose of FDA labeling requirements and the ways in which Defendant allegedly failed to satisfy those requirements.

Specific Causation Opinions and Prognosis

Defendant also seeks to exclude all of Dr. Hoyte's opinions regarding specific causation as unsupported by the record and based on an unreliable methodology. Defendant specifically argues that Dr. Hoyte's opinions are based on a deficient and unreliable differential diagnosis because he failed to address multiple alternative causes for each of the medical conditions that he claims are attributable to the Avaulta.

Upon review of the record, including Dr. Hoyte's expert report and deposition, the Court finds that Dr. Hoyte has conducted a "sufficiently reliable differential diagnosis" to support his case-specific opinions. *See* (Docs. 62-2; 62-3); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 627 (finding that Dr. Hoyte performed a sufficiently reliable differential diagnosis where he ruled out any fault of the surgeon and effectively ruled out "other possibilities by suggesting that, to a reasonable degree of medical certainty, the complications experienced by the bellwether plaintiffs are so consistent with those that Dr. Hoyte has observed and experienced that nothing other than the mesh could be the cause"). As such, the Court finds that Dr. Hoyte's

opinions – including his opinions on design defects and Plaintiff's prognosis – are supported by the record, sufficiently reliable, and admissible. Defendant's request to exclude all of Dr. Hoyte's specific causation opinions is denied.

Safer Alternatives to the Avaulta

Defendant argues that Dr. Hoyte's opinion that there were safer alternatives to the Avaulta to treat Plaintiff should be excluded. The Court disagrees. First, Dr. Hoyte is not required to personally test any or all of the "safer alternatives" to the Avaulta for his opinions to be admissible. As the MDL court explained, Dr. Hoyte "clearly has knowledge of Avaulta products and the design of Avaulta products." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 624. Dr. Hoyte is qualified "by knowledge, skill, experience, training, or education to opine as to the design of Avaulta mesh products," regardless of whether he personally tested any of the alternative designs. *See id*. at 624–25.

Second, Dr. Hoyte's opinions on safer alternatives are relevant to this litigation. In other cases in this MDL, plaintiffs have been able to present expert evidence on safer alternative designs, including that the Avaulta product could have been designed with "polypropylene mesh with larger pores," or "rounder, thinner arms," or that the mesh could have been constructed with "native tissue." *See Dalton v. C. R. Bard, Inc.,* No. 3:19-CV-2484-D, 2020 WL 1307965, at *10–11 (N.D. Tex. Mar. 19, 2020); *Dahse v. C. R. Bard, Inc.*, No. 2:12-CV-02701, 2016 WL 7155770, at *4 (S.D. Va. Dec. 7, 2016). Consequently, Defendant's request to exclude Dr. Hoyte's opinions as to safer alternatives is denied.

Instructions for Use

Defendant argues that the Court should preclude Dr. Hoyte from rendering opinions concerning the Avaulta Instructions for Use (IFU). The MDL court previously found that Dr. Hoyte is "qualified to testify about whether the risks he perceives are in fact warned about in the IFU." *In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2187, 2018 WL 4220671, at *5. However, Judge Goodwin found that Dr. Hoyte – without additional expertise in the specific area of product warnings – is not qualified to opine on the adequacy of the warnings. *See id*. The Court sees no reason to depart from these rulings and adopts them herein. Consequently, Bard's motion is granted in part, and denied in part, as to Dr. Hoyte's opinions concerning the Avaulta IFU.

Other Opinions

Defendant asserts that Dr. Hoyte has either conceded that he will not provide, or has not provided opinions concerning: (1) the amount of damages that Plaintiff should be awarded; (2) the reasonableness or necessity of Plaintiff's medical bills or the cost of Plaintiff's care; (3) whether Plaintiff's vulvar nevus was caused by the Avaulta; (4) any opinion not set forth in his expert report or any differential diagnosis not set forth therein; (5) internal corporate documents; and (6) biomechanical testing that was done on the Avaulta. Defendant contends that Dr. Hoyte is not qualified to opine on any of these matters. In response, Plaintiff argues that Dr. Hoyte should be permitted to give opinions on these issues in this case.

After consideration, the Court denies without prejudice Defendant's request to exclude these opinions. This ruling does not preclude Defendant from objecting to or challenging Dr. Hoyte's opinions on these issues if offered at trial.

Accordingly, it is

ORDERED, ADJUDGED and **DECREED**:

"Defendant C. R. Bard's Motion to Exclude or Limit the Opinions and Testimony of Lennox Hoyte, M.D." is hereby **GRANTED IN PART** and **DENIED IN PART**, as set forth herein.

DONE and **ORDERED** in Chambers, in Fort Myers, Florida, this 9th day of April, 2020.

TOM BARBER
UNITED STATES DISTRICT JUDGE